



MGI PHARMA INC  
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# COMPLEMENTARY STRENGTHS IN ONCOLOGY

## LEAD US FORWARD

2001 ANNUAL REPORT

PROCESSED

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MGI  
PHARMA



Back Cover: **Dr. Michael Cullen Jr.**, Vice President of Clinical Affairs and Chief Medical Officer at MGI PHARMA, reviews clinical trial results.

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# ABOUT THE COMPANY

MGI PHARMA, Inc. is an oncology-focused pharmaceutical company that acquires, develops and commercializes differentiated products that address the unmet needs of cancer patients. MGI is building a balanced product portfolio of proprietary pharmaceuticals, and intends to become a leader in oncology. The Company's portfolio includes both revenue-generating marketed products as well as late-stage product candidates.

MGI currently has two compounds in late-stage development: palonosetron, a potent, highly selective 5-HT<sub>3</sub>-receptor antagonist with an extended half-life, is in development for the prevention of chemotherapy-induced nausea and vomiting. The pivotal Phase 3 trials of palonosetron were completed in January 2002, and submission of a New Drug Application is anticipated to occur in the third quarter this year. Also in late-stage development is irofulven, MGI's promising anti-cancer product candidate that is currently in a pivotal Phase 3 clinical trial in refractory pancreatic cancer patients, for which it has received FDA Fast Track designation. MGI is also developing MG98, a second-generation antisense compound in Phase 2 trials that targets the re-expression of silenced tumor suppressor genes, one of the most exciting molecular biology approaches for cancer treatment today.

MGI develops its oncology product candidates with a proven product development team, markets and promotes its commercial products in the United States through its highly experienced 60-person oncology sales organization, and collaborates with other pharmaceutical or biotechnology companies in international markets. MGI's commercial products include Salagen® Tablets (pilocarpine hydrochloride), Hexalen® (altretamine) capsules, and Didronel® (etidronate disodium) IV infusion.

The Company's management team is highly accomplished in the pharmaceutical industry, and plans to continue MGI's growth through a focused licensing and business development strategy. Its board of directors comprises both seasoned pharmaceutical industry executives and eminent physicians and clinicians. MGI associates share the vision of building a profitable, oncology-focused pharmaceutical business. We are striving to make a difference in the lives of cancer patients, and we take pride in our progress to date.

MGI PHARMA is based in Minneapolis, Minnesota, and its common stock is traded on The Nasdaq Stock Market®, under the symbol "MOGN." For additional information, please visit MGI's Web site at [www.mgipharma.com](http://www.mgipharma.com).

***TWO OF OUR KEY ASSETS  
HAVE HELPED POSITION  
MGI PHARMA FOR SUCCESS  
IN ONCOLOGY:***

**Charles N. Blitzzer**

President and Chief Executive Officer



# EXECUTIVE MESSAGE

## Dear Shareholders:

Once again, as I've done for the past five years, I'm pleased to report our Company's continued growth through record-breaking sales of our marketed products, the exceptional progress made in our clinical development programs, the broadening capabilities and expertise of our corporate infrastructure, and the successful completion of financing activities.

In addition to summarizing our achievements during 2001, this annual report to shareholders highlights two of MGI's key corporate assets: our proven product development team and our highly experienced commercial (sales and marketing) organization. These internal complementary strengths and proven capabilities will pave our way toward achieving our overall goal of establishing MGI as a leader in oncology. During 2001 we made substantial progress in building a robust portfolio of oncology products through our strategic combination of aggressive commercialization and clinical development activities.

## Our Achievements in 2001

We have made significant strides in accomplishing the milestones we set out to achieve in 2001. Progress in both our clinical development initiatives and commercial development programs included the following highlights:

- Acquiring the exclusive U.S. and Canadian licensing and distribution rights for palonosetron was clearly one of our landmark achievements in 2001. We formally signed this agreement with our partner HELSINN Healthcare SA of Lugano, Switzerland, in April. Palonosetron is a potent, highly selective 5-HT<sub>3</sub> antagonist, with a nearly 40-hour plasma half-life, in late-stage development for the prevention of chemotherapy-induced nausea and vomiting (CINV). Our enthusiasm for this product

candidate was based on results from a previous Phase 2 trial of palonosetron, which demonstrated an extended duration of activity, and we have submitted this data for presentation at the upcoming American Society of Clinical Oncology (ASCO) annual meeting in May 2002. The market for treating CINV is approximately \$1 billion in North America, and palonosetron has the potential to enter this growing market as a differentiated product.

- Shortly after the fourth quarter, we were pleased to announce the completion of the pivotal Phase 3 program for palonosetron. Development of this supportive care product candidate has proceeded on a well-characterized path, similar to other 5-HT<sub>3</sub> antagonists. Over 1,800 patients were treated in the Phase 3 program, and data collection and analysis is currently underway, with submission of a New Drug Application targeted for the third quarter of 2002. We intend to share with you an appropriate level of summary information on the Phase 3 trial results in the first half of 2002. As you can imagine, we are very excited about this important supportive care product and how it may help cancer patients better tolerate their chemotherapy.
- In 2001, we initiated a pivotal Phase 3 trial of irifulven, our novel chemotherapeutic agent, in patients with Gemzar®-refractory pancreatic cancer, for which we received Fast Track designation from the U.S. Food and Drug Administration (FDA). We continue to enroll patients in this pivotal Phase 3 trial of irifulven, and expect to complete enrollment during the second half of 2002. As many of you know, irifulven is the first product candidate in MGI's family of proprietary anti-cancer compounds called acylfulvenes. Irifulven's unique mechanism

*FOR MGI PHARMA, 2001 WAS A VERY GRATIFYING YEAR OF  
CONTINUED GROWTH AND ACHIEVEMENTS AS WE ADVANCE  
TOWARD OUR GOAL OF BECOMING A LEADER IN ONCOLOGY.*

of action allows it to retain activity against a variety of solid tumors, including drug-resistant cancers, and to be synergistic with several classes of approved cancer drugs.

- We continued to advance our evaluation of irofulven in 2001 as both monotherapy and combination therapy. Phase 2 trials in which patient enrollment was expanded – because the required anti-cancer activity was demonstrated – included hormone-refractory prostate, refractory ovarian, and inoperable liver cancer trials. We also initiated three more Phase 1 combination trials of irofulven with Gemzar®, with Taxotere®, and most recently with cisplatin, which augment the ongoing Phase 1 trial of irofulven with Camptosar®. All of the trials initiated in 2001 utilize the every-other-week dosing schedule of irofulven, which has demonstrated an improved tolerance profile and an ability to deliver comparable overall dose intensity to patients.

As you can see from this 2001 progress report, we are executing an aggressive development program for irofulven, merited, we believe, by its continuing clinical demonstration of activity against hard-to-treat tumors. We continue to be pleased with the progress of this drug candidate, and believe that irofulven holds promise to become an effective treatment for a variety of solid tumors.

- Along with our partner MethyGene Inc., of Montreal, Canada, we also initiated two additional Phase 2 trials of MG98, in renal cell carcinoma and most recently in myelodysplastic syndrome and acute myeloid leukemia. MG98 is a second-generation antisense compound that inhibits expression of DNA-methyltransferase, an enzyme that has been shown to be responsible for silencing tumor

suppressor genes. As a molecular-targeted therapy, MG98's favorable side-effect profile presents a potential clinical advantage relative to existing cancer therapies. MG98 has already shown anti-cancer activity in Phase 1 trials, so we are excited about the potential of this new approach to cancer therapy. The addition of a molecular-targeted therapy to our pipeline of chemotherapeutic agents and supportive care products further expands and balances MGI's oncology portfolio.

- In 2001, during one of our country's most challenging economic climates and toughest financial markets, MGI succeeded in raising a total of \$72 million in three financings, in May, October and November. This additional capital places MGI on solid financial footing and helps ensure that our Company has the necessary resources to bring palonosetron and irofulven to market. We feel it is a testament to our potential as a small biopharmaceutical company to have been able to fund our continued growth in the midst of such difficult external economic factors.

#### **MGI Business Results**

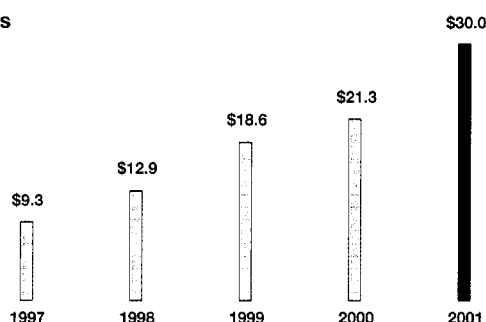
The year 2001 was another great year for MGI, in terms of revenues and sales, with Salagen® Tablets (pilocarpine hydrochloride) and Hexalen® (altretamine) capsules being the primary drivers. Total revenues increased 31 percent from the previous year to \$33 million in 2001, and annual product sales grew 41 percent from 2000 results to \$30 million in 2001. Despite the entrance of a competitor in the Sjögren's syndrome market in 2000, we have been able to retain the dominant market position of Salagen Tablets. We were pleased with the continued strong growth of Salagen Tablets sales in the U.S. in 2001, which rose 27 percent over the previous year.

# WE MADE SUBSTANTIAL PROGRESS IN BUILDING A ROBUST PORTFOLIO OF ONCOLOGY PRODUCTS THROUGH OUR AGGRESSIVE COMMERCIALIZATION AND CLINICAL DEVELOPMENT ACTIVITIES.

In March of 2001, MGI's sales force and marketing team began promoting Hexalen capsules to the medical and gynecological oncology community for the treatment of refractory ovarian cancer, providing important exposure to clinicians that could also become an audience for future palonosetron and irofulven promotion. In just the first nine months since its re-launch, Hexalen has exceeded our sales goal!

## Product Sales

In Millions



We remain extremely proud of our highly experienced, field sales specialists who have established relationships with clinical oncologists, cancer centers and other important oncology customers. We plan to further transition MGI to become a more commercially driven entity as palonosetron and irofulven move closer to New Drug Application submissions with the FDA. In 2002, our marketing activities will include preparation for the potential launches of palonosetron and irofulven.

It remains a corporate goal for MGI to sign a licensing agreement for irofulven and the acylfulvene family of compounds with a European partner. Despite our best intentions, this goal was not achieved in 2001. However, we continue active discussions with several interested potential partners. Fortunately, having cash on the balance sheet right now affords us the opportunity to select the right partner for the right reasons.

## Our Key Assets and Our Future

As an oncology-focused company, MGI is in a very enviable position because we have all the requisite assets in place to succeed and achieve our goal of becoming a leader in oncology. Today, MGI enjoys:

- A unique and balanced development-stage pipeline, featuring two product candidates in or having just completed Phase 3 trials;
- A proven product development team that has already achieved two New Drug Application approvals;
- Revenue-generating products and a highly specialized oncology sales and marketing organization;
- Retained economics downstream, meaning that MGI does not need to partner its products with others in the United States; and
- An exceptionally strong management team and board of directors whose goals are aligned with those of our shareholders.

In closing, I feel that the ensuing 12-month period could very well represent the best year ever for MGI and its shareholders. During my tenure as chief executive officer, we have made great strides in moving MGI up the maturation curve. We sit at the threshold of a bright future and I want each of you to know that we appreciate your patience and support. MGI associates continue to deliver on our promises with one salient goal in mind – to become a leader in oncology! We are convinced we are continually moving toward this goal.

Charles N. Blitzer  
President and Chief Executive Officer  
March 15, 2002



**WE ARE  
BECOMING A LEADER IN  
ONCOLOGY BY REALIZING  
THE POTENTIAL OF OUR  
PRODUCT PIPELINE,  
EXECUTING OUR STRATEGIES,  
AND ACHIEVING OUR GOALS.”**

# PRODUCT PORTFOLIO

## COMMERCIALIZED PRODUCTS:

**Salagen® Tablets** (pilocarpine hydrochloride) – Conceived, developed and marketed by MGI for the treatment of radiation-induced chronic dry mouth symptoms in head and neck cancer patients, and for the treatment of dry mouth symptoms in patients with Sjögren's syndrome, an autoimmune disease that damages the salivary glands. Salagen Tablets are the first prescription drug approved in the United States for these indications, and have become the standard of care for these patients.

**Hexalen®** (altretamine) capsules – An oral, second-line chemotherapy approved in the United States for the treatment of refractory ovarian cancer. Hexalen capsules have induced complete responses in patients refractory to first-line therapy and provide the convenience of oral dosing administration.

**Didronel®** (etidronate disodium) IV infusion – For the treatment of hypercalcemia (elevated blood calcium) in late-stage cancer patients.

## PRODUCTS UNDER DEVELOPMENT:

**Palonosetron** – A potent, highly selective 5-HT<sub>3</sub>-receptor antagonist with an extended half-life in late-stage development for the prevention of chemotherapy-induced nausea and vomiting. Pivotal Phase 3 trials of palonosetron were completed in January 2002. The extended half-life of palonosetron and clinical trial results assessing efficacy beyond 24 hours may differentiate palonosetron. If approved for marketing, palonosetron will compete in the \$1 billion North American market for 5-HT<sub>3</sub> antagonists.

**Irofulven** – MGI's promising chemotherapeutic agent is currently in a pivotal Phase 3 clinical trial in gemcitabine-refractory pancreatic cancer patients, for which it received FDA Fast Track designation.

Irofulven is the lead drug candidate in MGI's novel family of proprietary anti-cancer compounds called the acylfulvenes. Irofulven exhibits a unique mechanism of action compared to current anti-cancer drugs, leading to selective apoptotic or programmed cell death of tumor cells. MGI is developing irofulven through a series of clinical trials where it has demonstrated anti-cancer activity against a variety of solid tumors, including pancreatic, ovarian and prostate cancers. Irofulven is both active against drug-resistant cancers and synergistic with certain approved cancer drugs. MGI holds exclusive worldwide rights to irofulven, and has a strong worldwide patent position.

**Acylfulvene analogs** – In addition to irofulven, other acylfulvene analogs are being evaluated to determine their potential as anti-cancer drugs. A group of analogs are undergoing preclinical testing.

**MG98** – A second-generation antisense compound being developed for the purpose of blocking production of DNA methyltransferase, which is associated with silencing tumor suppressor genes via hypermethylation. Re-expression of tumor suppressor genes that have been silenced by hypermethylation is considered one of the most exciting new approaches for molecular-targeted cancer therapy. MG98 is being studied in a series of Phase 2 trials after demonstrating anti-cancer activity in a Phase 1 trial. In preclinical models, MG98 used alone and in combination with other anti-cancer agents has caused shrinkage or inhibited growth of human tumors.

**Small molecule DNA methyltransferase inhibitors** – Along with MG98, MGI is developing complementary small molecule DNA methyltransferase inhibitors for anti-cancer activity. Both programs represent different molecular-targeting approaches for the same nuclear enzyme and have the potential to treat a wide variety of tumor types.

## Commercialized Products

### Salagen® Tablets

Head and Neck Cancer

Diabetes Syndrome

### Hexalen® Capsules

### Didronel® IV Infusion

Preclinical

Phase 1

Phase 2

Phase 3

Market

## Products Under Development

### Palonosetron

### Trifluven

Anticancer

Prostate

Prostate - hormone refractory

Prostate - metastatic

Prostate - metastatic

Prostate

Prostate

Combination with Camptosar®

Combination with Gemzar®

Combination with Taxotere®

Combination with Cisplatin

### Acylfulvene Analogs

### MG98

Anti

Anti/AMI

### DNA Methyltransferase Inhibitors

Research is sponsored by the National Cancer Institute

under a Cooperative Agreement

Preclinical

Phase 1

Phase 2

Phase 3

Market

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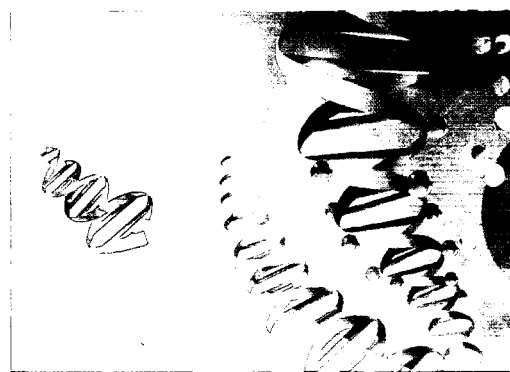
**Palonosetron** A supportive care product candidate for the prevention of chemotherapy-induced nausea and vomiting.

**Irofulven** A promising chemotherapeutic compound with a unique mechanism of action with potential to treat a wide variety of cancers.

**MG98** A second-generation antisense compound that targets an important enzyme linked to the control of gene expression and tumor growth.

# MAXIMIZING OUR DEVELOPMENT EXPERTISE

**Dr. John MacDonald**, Senior Vice President, Development, studies patient CT-101 with **Sheri Smith**, Director of Clinical Development.



## BROADENING MGI PHARMA'S CAPABILITIES

### Proven Product Development Team

One of MGI's major corporate assets is its proven product development team. Our research and development capability demonstrates great breadth, with oncology product candidates in all phases of clinical trials. By working closely with the U.S. Food and Drug Administration (FDA), MGI has already achieved two drug approvals for Salagen® Tablets – the first prescription drug approved in the United States for its indications.

This accomplished product development team of research scientists, clinicians, biostatisticians, pharmacologists, and regulatory affairs experts has grown and broadened its capabilities and range of expertise. As MGI has sharpened its focus on oncology drug development and meeting the needs of cancer patients, our development team has taken irofulven from its initial test tube stage into a pivotal Phase 3 clinical trial, which could serve as the basis for regulatory approval of irofulven in the United States and Europe.

### Moving Our Research Forward

Our R&D team is currently testing irofulven in a series of clinical trials where it has demonstrated anti-tumor activity against solid tumors, including pancreatic, ovarian and prostate cancers. In February 2001, MGI initiated a pivotal Phase 3 trial of irofulven in advanced-stage, gemcitabine-refractory pancreatic cancer patients – for which our development team received FDA Fast Track designation in June 2001. With full enrollment targeted to occur in the second half of 2002, MGI anticipates submitting a New Drug Application in the first half of 2003, assuming favorable trial results.

In addition to studying irofulven as a single agent, our product development team has initiated drug combination trials of irofulven with Camptosar® (CPT-11 or irinotecan), with Gemzar® (gemcitabine hydrochloride), with Taxotere® (docetaxel) and with cisplatin.

In 2001, our team also advanced the development of MG98 in Phase 2 trials. MGI is developing MG98, a second-generation antisense compound, under an exclusive North American license, research and development agreement for inhibitors of DNA methyltransferase with our partner MethylGene Inc., of Montreal, Canada. Re-expression of silenced tumor suppressor genes is considered one of the most exciting new approaches for molecular-targeted cancer therapy in the post-genomic era. MGI's development team is working with MethylGene researchers to further evaluate MG98 in cancers where silencing of tumor suppressor genes by DNA methyltransferase has been documented. A Phase 1/Phase 2 trial of MG98 in myelodysplasia and acute myeloid leukemia was initiated in January 2002.

### Impressive Results

Encouraging data from our preclinical and clinical trials, including important objective tumor responses, were presented at more than half a dozen important cancer research and scientific meetings in 2001, including the American Association for Cancer Research and the American Society of Clinical Oncology. To achieve these clinical results, MGI's development team collaborates with prominent outside clinical investigators, scientific advisors, the National Cancer Institute, and our partners MethylGene and HELSINN Healthcare SA. We are pleased to be working with highly respected physicians at major cancer research centers throughout the world as well as with talented international partners.

MGI is extremely proud of its R&D track record and the progress we continue to see in our clinical trials as we develop novel therapeutic agents and supportive care products to treat cancer patients.

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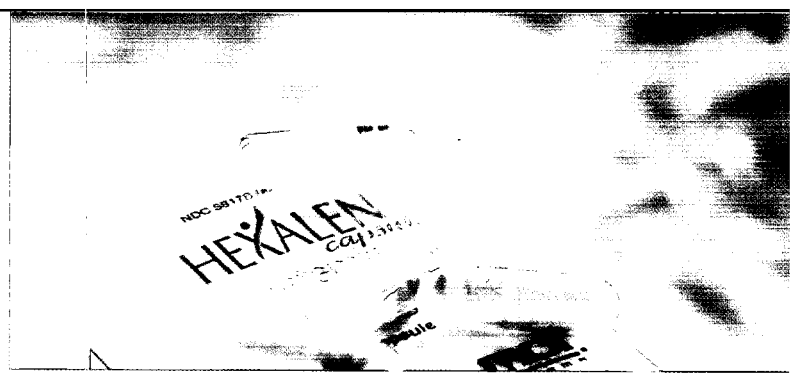
**Salagen® Tablets** The first prescription drug approved in the U.S. to treat the symptoms of dry mouth from radiation treatment in head and neck cancer patients and in Sjögren's syndrome patients.

**Hexalen® Capsules** Offers women with ovarian cancer another chance for response and prolonged survival.

# OPTIMIZING OUR OPPORTUNITIES



**Lonnie Moulder**, Executive Vice President of MGI PHARMA (center), visits with **Riccardo Braggia** (left) and **Enrico Braggia** (right), managing directors of **Novartis Healthcare SA**, our palonosetron partners based in Lugano, Switzerland.



## IMPLEMENTING ELEMENTS FOR GROWTH

### Experienced Commercial Organization

One of our major corporate assets at MGI is our commercial organization, which comprises our highly experienced, 100-person sales organization, the creative talents of our marketing team, and our resourceful business development group. MGI's business development activities, sales force and marketing capabilities are significant factors in our successful introduction of new products and the continued strong sales of our current commercial products.

In 2001, our sales and marketing teams once again successfully defended the leading market position of Salagen Tablets and grew sales by an impressive 27 percent over last year. This is no small feat considering increased competition in the marketplace. MGI's expanded sales organization consists of highly specialized professionals who know the oncology marketplace and have established relationships with oncology physicians, nurses, pharmacists and other key personnel at clinics, hospitals and cancer centers.

### Powerful Partnerships, Retained Economics

MGI's commercial operations group is focused on optimizing the business opportunity for our oncology products that address large unmet medical needs and have substantial commercial potential. MGI markets its products in the United States and partners with others in international markets. Recognizing the capabilities and quality of our commercial organization as a key MGI strength, we are able to retain marketing rights in the United States, the single largest market for pharmaceutical products.

Outside the United States, MGI markets Salagen Tablets through its long-time partners, Pharmacia Corporation in Canada and Novartis throughout Europe.

One of MGI's business development highlights in 2001 was the April signing of a definitive agreement with HELSINN Healthcare SA, a privately-owned pharmaceutical group with headquarters in Switzerland, granting MGI the exclusive U.S. and Canadian licensing and distribution rights to palonosetron.

### Adding To Our Oncology Product Portfolio

In late 2000, MGI acquired the exclusive worldwide rights to Hexalen capsules, a second-line therapy for patients with persistent and recurrent ovarian cancer. In spring 2001, our sales and marketing teams successfully re-launched the direct promotion of Hexalen capsules, and are now providing the resource promotional attention and support to re-establish Hexalen as a viable, second-line ovarian cancer therapy. MGI exceeded its 2001 sales goals for Hexalen, selling the product primarily to gynecological and medical oncologists. In addition to generating additional revenue, this product provides synergy for our sales and marketing efforts with our existing and future oncology product offerings.

Palonosetron is a potent, highly selective 5-HT<sub>3</sub>-receptor antagonist with a long half-life, in development in North America and Europe for the prevention of chemotherapy-induced nausea and vomiting (CINV). If untreated, CINV is estimated to occur in 85 percent of cancer patients undergoing chemotherapy.

MGI and its partner HELSINN announced the completion of the pivotal Phase 3 trials of palonosetron in January 2002. With submission of the New Drug Application for palonosetron planned to occur in the third quarter of 2002, MGI's commercial team is now in a pre-launch mode, and will be ready to launch palonosetron in 2003. If approved, palonosetron will compete in the \$1 billion North American CINV treat-

ment market.

# FINANCIAL HIGHLIGHTS

— Per share—except per share data

Year Ended December 31,	1997	1998	1999	2000	2001
<b>Statements of Operations Data:</b>					
<b>Revenues:</b>					
Sales	\$ 9,345	\$ 12,945	\$ 18,643	\$ 21,333	\$ 30,022
Licensing	—	756	1,088	770	—
Other	3,275	3,342	4,955	3,109	2,932
	12,620	17,043	24,686	25,212	32,954
<b>Costs and Expenses:</b>					
Cost of sales	768	939	1,209	1,627	3,633
Selling, general and administrative	9,339	10,989	12,713	18,295	28,463
Research and development	4,989	5,302	6,677	17,241	36,101
Amortization	—	—	—	98	1,182
	14,096	17,230	20,599	37,261	69,379
Income (loss) from operations	(2,476)	(187)	4,087	(12,049)	(36,425)
Interest income	876	806	966	2,146	1,600
Income (loss) before taxes and cumulative effect of change in accounting principle	(1,600)	619	5,053	(9,903)	(34,825)
Provision for income taxes	185	205	321	148	—
Net income (loss) before cumulative effect of change in accounting principle	(1,785)	414	4,732	(10,051)	(34,825)
Cumulative effect of change in accounting principle	—	—	—	(9,403)	—
Net income (loss)	\$ (1,785)	\$ 414	\$ 4,732	\$ (19,454)	\$ (34,825)
<b>Net income (loss) per common share:</b>					
<b>Basic:</b>					
Income (loss) before effect of accounting change	\$ (0.13)	\$ 0.03	\$ 0.32	\$ (0.63)	\$ (1.74)
Cumulative effect of accounting change	—	—	—	(0.59)	—
Net income (loss)	\$ (0.13)	\$ 0.03	\$ 0.32	\$ (1.22)	\$ (1.74)
<b>Assuming dilution:</b>					
Income (loss) before effect of accounting change	\$ (0.13)	\$ 0.03	\$ 0.30	\$ (0.63)	\$ (1.74)
Cumulative effect of accounting change	—	—	—	(0.59)	—
Net income (loss)	\$ (0.13)	\$ 0.03	\$ 0.30	\$ (1.22)	\$ (1.74)
<b>Weighted average number of common shares outstanding:</b>					
Basic	14,116	14,368	14,742	15,990	19,985
Assuming dilution	14,116	14,966	15,633	15,990	19,985

December 31,	1997	1998	1999	2000	2001
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and marketable investments	\$ 15,056	\$ 17,081	\$ 24,151	\$ 29,899	\$ 77,712
Working capital	\$ 13,981	\$ 16,096	\$ 23,240	\$ 26,042	\$ 63,182
Assets	\$ 18,191	\$ 21,122	\$ 28,974	\$ 52,744	\$ 97,668
Total liabilities	\$ 3,172	\$ 4,011	\$ 4,329	\$ 26,698	\$ 28,733
Accumulated deficit	\$(74,243)	\$(73,828)	\$(69,097)	\$(88,551)	\$(123,376)
Net stockholders' equity	\$ 15,019	\$ 17,111	\$ 24,644	\$ 26,046	\$ 68,935

— MCF/ARMA



# MANAGEMENT'S DISCUSSION AND ANALYSIS

## Overview

We are an oncology-focused pharmaceutical company that acquires, develops and commercializes proprietary products that address unmet needs of cancer patients. We focus our direct sales efforts solely within the United States and create alliances with other pharmaceutical or biotechnology companies for the commercialization of our products in other countries.

We promote products directly to physician specialists in the United States using our own sales force. These products include our Salagen® Tablets (pilocarpine hydrochloride), Hexalen® (altretamine) capsules, and Didronel® (etidronate disodium) IV infusion. We also sell Mylocel™ (hydroxyurea) tablets under an exclusive marketing and distribution agreement with Barr Laboratories. Salagen Tablets are approved in the United States for two indications: the symptoms of dry mouth associated with radiation treatment in head and neck cancer patients and the symptoms of dry mouth associated with Sjögren's syndrome, an autoimmune disease that damages the salivary glands. Sales of Salagen Tablets in the United States accounted for 87 percent of our product sales during 2001. Hexalen capsules, which we began selling after we acquired the product from MedImmune Inc. in November 2000, is an orally administered chemotherapeutic agent approved in the United States for treatment of refractory ovarian cancer patients. Didronel IV infusion is approved for the treatment of hypercalcemia (elevated blood calcium) in late-stage cancer patients. Mylocel tablets are approved for the treatment of melanoma, resistant chronic myelocytic leukemia, and recurrent, metastatic, or inoperable carcinoma of the ovary.

Outside the United States, we commercialize our products through various alliances from which we recognize licensing revenues. We have licensing agreements with several international pharmaceutical companies to develop and commercialize Salagen Tablets in Europe, Canada and Japan. Exclusive rights in Japan to irifolven and the other acylfulvene analogs were granted to Dainippon under a development and commercialization agreement in 1995. We rely on third parties to manufacture our commercialized and development stage products.

In April 2001, we obtained the exclusive U.S. and Canadian license and distribution rights to palonosetron, a cancer supportive care product candidate for the prevention of chemotherapy-induced nausea and vomiting, which recently completed its Phase 3 trials. Our current product development efforts also

include a series of clinical trials for irifolven, the lead product candidate in our novel family of proprietary cancer therapy compounds called the acylfulvenes. We are also developing MG98 and other inhibitors of DNA methyltransferase for North American markets. DNA methyltransferase is an enzyme that has been associated with uncontrolled tumor growth. We also provide ongoing clinical support of Salagen Tablets.

## Results of Operations

### Critical Accounting Policies

In preparing our financial statements in conformity with accounting principles generally accepted in the United States, our management must make decisions which impact reported amounts and related disclosures. Such decisions include the selection of the appropriate accounting principles to be applied and the assumptions on which to base accounting estimates. In reaching such decisions, our management applies judgment based on our understanding and analysis of relevant circumstances. Note 1 to the financial statements provides a summary of the significant accounting policies followed in the preparation of the financial statements. Our critical accounting policies include the following:

Our accounting policy on revenue recognition is fully described in Notes 1, 7 and 8 to the financial statements. The majority of our revenue relates to product sales for which revenue is recognized upon shipment, with limited judgment required related to product returns. Licensing revenue recognition requires management to estimate effective terms of agreements and identify points at which performance is met under the contracts such that the revenue earnings process is complete. Under this policy for out-licensing arrangements, revenue related to up-front, time-based and performance-based licensing payments is recognized over the entire contract performance period. For our major licensing contracts, this results in the deferral of significant revenue amounts (approximately \$10.6 million at December 31, 2001) where non-refundable cash payments have been received, but the revenue is not immediately recognized due to the long-term nature of the respective agreements. Following our initial estimate of the effective terms of these arrangements, subsequent developments could lengthen or shorten the period over which the deferred revenue is recognized.

Research and development expense includes work performed for us by outside vendors and research organizations. At each reporting period, we estimate expenses incurred but

not yet reported or billed to us by these outside vendors. These expense estimates typically cover a period of 1 to 4 weeks of expense. Actual results are recorded on a timely basis and have, historically, not been materially different from our estimates. In addition, costs related to in-licensing arrangements for product candidates that have not yet received market approval are expensed as research and development.

## Revenues

**Sales:** Sales revenue increased 14 percent from \$18,643,168 in 1999, to \$21,333,229 in 2000, and increased 41 percent to \$30,021,813 in 2001. The increases in sales revenue reflect increased revenue from Salagen Tablets, resulting from an increase in demand, an increase in stocking of inventory by wholesalers and retail pharmacies, and an increase in selling price. The increases in sales revenue also reflect revenue from Hexalen capsules, which we purchased from MedImmune Inc. in November 2000, with sales commencing in December 2000, and active field promotion commencing in March 2001.

Sales of Salagen Tablets in the United States provided 97 percent of our sales revenue in 1999, 96 percent in 2000, and 87 percent in 2001. As is common in the pharmaceutical industry, our domestic sales are made to pharmaceutical wholesalers for further distribution through pharmacies to the ultimate consumers of our products. Future sales of Salagen Tablets are expected to moderate due to competition from other products and moderating growth in the Sjögren's syndrome portion of the market. We expect sales revenue for all of our products in 2002 to be approximately \$30 million.

**Promotion:** Promotion revenue decreased 29 percent from \$1,087,852 in 1999 to \$769,874 in 2000. We did not recognize any promotion revenue in 2001. The decreases in promotion revenue reflect changes in our product promotion relationships. In 1999, we were promoting products under agreements with Schein Pharmaceutical for INFeD® (iron dextran injection), Pharmacia Corporation for Azulfidine EN-tabs® (sulfasalazine delayed release tablets, USP) and Connerics Corporation for Ridaura® (auranofin) and Luxiq® (betamethasone valerate). Under the INFeD agreement, we recognized promotion revenue of \$337,852 in 1999, based on certain sales call and product sales activity. The INFeD agreement concluded in 1999. Under the Ridaura agreement, we recognized \$750,000 in promotion revenue in 1999 and \$750,000 in 2000, based on achieving certain sales call activity. The agreements for Ridaura and Luxiq concluded in the third quarter of 2000. We did not recognize any revenue for Luxiq during the term of that agreement. We

concluded the Azulfidine-EN Tabs agreement in the first half of 2001, without the recognition of any promotion fee revenue from this agreement.

**Licensing:** Licensing revenue decreased 37 percent from \$4,954,468 in 1999 to \$3,109,470 in 2000, and decreased six percent to \$2,932,007 in 2001. In 2000, the Company adopted Staff Accounting Bulletin No. 101 (SAB 101), "Revenue Recognition in Financial Statements" and recorded a cumulative effect of this change in accounting principle for previously received, non-refundable licensing payments. This resulted in a \$9.4 million one-time, non-cash charge and a corresponding increase in deferred revenue effective as of the beginning of 2000. This deferred amount is being amortized into license revenue over the expected periods of benefit for the related collaborative arrangements.

If SAB 101 had been applied retroactively, licensing revenue would have been \$3,384,011 in 1999. The decreases in licensing revenue from 1999 (assuming retroactive restatement) to 2000, and from 2000 to 2001 resulted from decreasing herbicide royalties, partially offset by increasing revenue from international Salagen Tablets relationships.

Licensing revenue is a combination of deferred revenue amortization from multiple element arrangements and of royalties which are recognized when the related sales occur. In 2000, we received milestone payments of \$830,000 from Kissei related to the development of Salagen Tablets in Japan, \$750,000 from Novartis Ophthalmics AG related to the licensing of Salagen Tablets in Europe, and \$650,000 from Dainippon related to acylfulvene rights in Japan. In 2001, we received a milestone payment of \$750,000 from Novartis Ophthalmics AG related to the licensing of Salagen Tablets in Europe. We recognized \$918,778 and \$841,258 of amortized deferred revenue in 2000 and 2001, respectively, related to all payments received under these license agreements. We will recognize the December 31, 2001 unamortized balance of \$10,622,606 from our license agreements into licensing revenue over the expected periods of benefit for the related collaborative arrangements. For 2002, we expect to amortize \$794,383 of deferred revenue into licensing revenue.

Future licensing revenue will fluctuate from quarter to quarter depending on the level of recurring royalty generating activities, and changes in amortization of deferred revenue, including the initiation or termination of licensing arrangements. We expect licensing revenue for 2002 to be approximately \$3 million.

## Costs and Expenses

**Cost of sales:** Cost of sales as a percent of sales was six percent for 1999, eight percent for 2000 and 12 percent for 2001. The increases result from a change in our product mix, including the addition of Hexalen capsules and Mylocel tablets to our oncology product portfolio. We believe that cost of sales as a percent of product sales for our marketed products for 2002 will range from 10 to 15 percent, as a result of changes in the product mix and increasing production costs.

**Selling, general and administrative:** Selling, general and administrative expenses increased 44 percent from \$12,713,287 in 1999 to \$18,294,757 in 2000, and increased 56 percent to \$28,463,387 in 2001. The increase from 1999 to 2000 resulted primarily from costs associated with the expansion of our U.S. based sales force by approximately two-thirds during the first half of 2000. The increase from 2000 to 2001 primarily resulted from increased costs related to our expanded business objectives, such as costs associated with the expansion of our U.S. based sales force, costs related to commencement of active field promotion in March 2001 of Hexalen capsules and Mylocel tablets, costs associated with the growth in the number of corporate-based associates, and increased facility costs in conjunction with our move to a new office location in June 2001. As described in Note 14, the Company uses a related party for consulting services, with \$87,000, \$172,000 and \$101,000 of related party consulting costs included in selling, general and administrative expense for 1999, 2000 and 2001, respectively. We expect selling, general and administrative expenses for 2002 to be approximately \$29 million.

**Research and development:** Research and development expense increased 158 percent from \$6,677,435 in 1999 to \$17,241,217 in 2000, and increased 109 percent to \$36,101,373 in 2001. Both increases include non-recurring license payments: \$5.7 million in 2000 related to our license agreement with MethylGene Inc., and \$13 million in 2001 related to our license agreement for palonosetron. Exclusive of non-recurring license payments, research and development expense increased 70 percent from \$6,627,435 in 1999 to \$11,266,217 in 2000, and increased 104 percent to \$23,035,123 in 2001.

Excluding non-recurring license payments, the increases reflect the expanded development of irifulven, the lead candidate in our novel family of proprietary compounds called the acylfulvenes, and expenses related to the development of MG98 and other inhibitors of DNA methyltransferase under a license that began in the third quarter of 2000. The increasing development expense of irifulven primarily relates to expansion of both the number of clinical trials and the number of patients

enrolled in those trials. A series of clinical trials were initiated and are at varying stages of completion. These trials are designed to evaluate the efficacy and safety of irifulven administered as a single chemotherapy agent and in combination with marketed chemotherapy agents for the treatment of patients with solid tumor cancers who are generally refractory to current therapies. We expect research and development expense for 2002 to be approximately \$45 million, which estimates \$14 million of non-recurring license payments related to palonosetron.

**Tax expense:** Our effective tax rate was six percent in 1999, reflecting a 10 percent foreign tax rate on Dainippon licensing payments and a two percent tax rate for alternative minimum tax. The tax amount for 2000 reflects the 10 percent foreign tax rate on licensing payments received. The tax rate for 2001 was zero, due to the absence of similar foreign cash receipts.

In 2001, we had a net loss of \$34,825,322, and as of December 31, 2001 we had an accumulated deficit of \$123,375,993. Our ability to achieve profitable operations is likely dependent upon our successful launch of palonosetron or irifulven, and therefore, we continue to maintain a valuation allowance against our deferred tax asset.

## Interest Income

Interest income increased 122 percent from \$966,434 in 1999 to \$2,145,553 in 2000, but decreased 25 percent to \$1,600,363 in 2001. The increase from 1999 to 2000 is a result of a higher average amount of funds available for investment from 1999 to 2000. Funds available in 2000 increased as a result of the sale of stock in the second quarter of 2000. The decrease from 2000 to 2001 is a result of a decrease in the investment yield, partially reduced by an increase in the average amount of funds available for investment. Funds available in 2001 increased as a result of the sales of stock in the second and fourth quarters of 2001. Interest income for 2002 will fluctuate depending on the timing of cashflows and changes in interest rates for marketable securities.

## Net Income (Loss)

We had net income of \$4,731,499 in 1999. We had a net loss of \$19,453,822 in 2000, which included a non-cash charge of \$9,402,643 relating to the adoption of SAB 101, and a net loss of \$34,825,322 in 2001. The change from net income in 1999 to a net loss in 2000 reflects a two percent increase in revenues from 1999 to 2000, and an 81 percent increase in costs and expenses from 1999 to 2000, including a 158 percent increase in research and development expense. The increased

net loss from 2000 to 2001 reflects a 31 percent increase in revenues from 2000 to 2001, and an 86 percent increase in costs and expenses from 2000 to 2001, including a 109 percent increase in research and development. During the next several years, we expect to direct our efforts towards activities intended to grow long-term revenues, including expanded development of irofulven and other product candidates. Increased spending on these initiatives, including development of MG98 and development milestones for palonosetron, will likely result in substantial net losses until after our successful launch of palonosetron or irofulven. We expect a net loss for 2002 of approximately \$45 million.

### Liquidity and Capital Resources

At December 31, 2001, we had cash and marketable investments of \$77,712,480 and working capital of \$63,181,509, compared with \$29,898,787 and \$26,041,813, respectively, at December 31, 2000. Our cash and marketable investment balance at December 31, 2001 includes \$4,000,000 in restricted cash for a pending milestone payment related to the license of palonosetron. In the year ended December 31, 2001, we received \$72,117,460 in net cash proceeds from the sale of shares of stock in the second and fourth quarters of 2001, \$2,200,000 in cash as a deposit from one of our international partners, and \$1,336,995 in cash from issuance of shares under stock award plans. We used \$17,420,273 of cash to fund our operating activities. We also paid \$4,800,000 related to the acquisition of Hexalen capsules, paid \$3,000,000 to increase our equity investment in MethylGene Inc., and purchased \$2,588,234 in equipment and furniture, primarily related to the move to our new facility in June 2001.

Substantial amounts of capital are required for pharmaceutical development and commercialization efforts. For continued development and commercialization of our product candidates and marketed products, and the acquisition and development of additional product candidates, we plan to utilize cash provided from product sales, collaborative arrangements and existing liquid assets. We will seek other sources of funding, including additional equity or debt issuances as appropriate. We expect cash use for 2002 to be approximately \$40,000,000, which includes cash required to fund operating activities and pay \$1,200,000 to MedImmune Inc. related to the purchase of Hexalen capsules. We have no arrangements or covenants that would trigger acceleration of our lease obligations or long-term liabilities.

Our liquidity is affected by a variety of factors, including sales of our products, the pace of our research and development programs, the in-licensing of new products and our ability to raise additional debt or equity capital. As identified in our risk factors, adverse changes that affect our continued access to the capital markets, continued development and expansion of our product candidates, and future demand for our marketed products would affect our longer-term liquidity. We believe we have sufficient liquidity and capital resources to fund all known cash requirements for the next 12 months. Our significant noncancellable contractual commitments are summarized in the following table:

	Lease	Hexalen Acquisition	Total
2002	\$1,575,000	1,200,000	\$2,775,000
2003	\$1,601,000	—	\$1,601,000
2004	\$1,622,000	—	\$1,622,000
2005	\$1,498,000	—	\$1,498,000
2006	\$1,229,000	—	\$1,229,000
Thereafter	\$1,776,000	—	\$1,776,000

At December 31, 2001, 100,000 shares remain registered for sale from shelf registration statements that were filed for 5 million shares with the Securities and Exchange Commission. These remaining shares pertain to an option that we granted to Ramius Securities, LLC, to purchase 100,000 shares of our common stock at prices ranging from \$16.95 to \$24.72 per share. This option, which expires on February 28, 2003, relates to a financing facility with Ramius Securities and Ramius Capital Group, LLC. Upon depletion of the shares available from the shelf registration, and absent current plans to utilize the Ramius financing facility, we expensed all deferred financing costs related to this facility in the fourth quarter of 2001. We recognized a non-cash charge of \$516,604 in selling, general and administrative expense for the value of the stock option as determined at the initiation of the financing facility.

### Selected Quarterly Operating Results

The following table shows our unaudited financial information for each of the quarters in the two year period ended December 31, 2001. In our opinion, this unaudited quarterly information has been prepared on the same basis as the audited financial statements and includes all adjustments (consisting only of normal recurring adjustments) necessary for a fair presentation of the information for the quarters presented, when read in conjunction with the financial statements and notes included elsewhere in this annual report. We believe that quarter-to-quarter comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of future performance.

Three months ended (in thousands except per share data)	March 31, 2000	June 30, 2000	Sept. 30, 2000	Dec. 31, 2000	March 31, 2001	June 30, 2001	Sept. 30, 2001	Dec. 31, 2001
<b>Revenues:</b>								
Sales	\$ 4,566	\$6,134	\$ 4,860	\$ 5,773	<b>\$ 6,984</b>	<b>\$ 10,161</b>	<b>\$ 5,993</b>	<b>\$ 6,884</b>
Promotion	250	270	250	—	—	—	—	—
Licensing	361	897	1,219	632	<b>592</b>	<b>851</b>	<b>957</b>	<b>532</b>
	5,177	7,301	6,329	6,405	<b>7,576</b>	<b>11,012</b>	<b>6,950</b>	<b>7,416</b>
<b>Cost and expenses:</b>								
Cost of sales	304	393	332	598	<b>789</b>	<b>1,032</b>	<b>757</b>	<b>1,055</b>
Selling, general & administrative	3,521	4,640	4,467	5,668	<b>6,493</b>	<b>7,283</b>	<b>6,552</b>	<b>8,135</b>
Research and development	1,804	2,225	8,575 <sup>2</sup>	4,636	<b>3,554</b>	<b>18,189<sup>3</sup></b>	<b>5,807</b>	<b>8,551</b>
Amortization	—	—	—	98	<b>295</b>	<b>296</b>	<b>296</b>	<b>295</b>
	5,629	7,258	13,374	11,000	<b>11,131</b>	<b>26,800</b>	<b>13,412</b>	<b>18,036</b>
Income (loss) from operations	(452)	43	(7,045)	(4,595)	<b>(3,555)</b>	<b>(15,788)</b>	<b>(6,462)</b>	<b>(10,620)</b>
Interest income	373	539	687	546	<b>436</b>	<b>378</b>	<b>415</b>	<b>371</b>
Income (loss) before taxes	(79)	582	(6,358)	(4,049)	<b>(3,119)</b>	<b>(15,410)</b>	<b>(6,047)</b>	<b>(10,249)</b>
Provision for income taxes	61	35	52	—	—	—	—	—
Net income (loss) before cumulative effect of change in accounting principle	(140)	547	(6,410)	(4,049)	<b>(3,119)</b>	<b>(15,410)</b>	<b>(6,047)</b>	<b>(10,249)</b>
Cumulative effect of change in accounting principle	(9,403) <sup>1</sup>	—	—	—	—	—	—	—
Net income (loss)	<b>\$(9,543)</b>	<b>\$ 547</b>	<b>\$(6,410)</b>	<b>\$(4,049)</b>	<b>\$(3,119)</b>	<b>\$(15,410)</b>	<b>\$(6,047)</b>	<b>\$(10,249)</b>
<b>Net income (loss) per common share:</b>								
Basic and diluted:								
Income (loss) before accounting change	\$ (0.01)	\$ 0.03	\$ (0.39)	\$ (0.25)	<b>\$ (0.19)</b>	<b>\$ (0.81)</b>	<b>\$ (0.29)</b>	<b>\$ (0.44)</b>
Cumulative effect of accounting change	(0.62)	—	—	—	—	—	—	—
Net income (loss)	<b>\$ (0.63)</b>	<b>\$ 0.03</b>	<b>\$ (0.39)</b>	<b>\$ (0.25)</b>	<b>\$ (0.19)</b>	<b>\$ (0.81)</b>	<b>\$ (0.29)</b>	<b>\$ (0.44)</b>
<b>Weighted average number of common shares:</b>								
Basic	15,217	15,812	16,452	16,470	<b>16,533</b>	<b>18,988</b>	<b>20,987</b>	<b>23,348</b>
Assuming dilution	15,217	17,161	16,452	16,470	<b>16,533</b>	<b>18,988</b>	<b>20,987</b>	<b>23,348</b>

1 Represents the cumulative effect of the adoption of SAB 101. 2 Includes \$5.7 million in license payments for MethylGene. 3 Includes \$13 million in license payments for palonosetron.

### Cautionary Statement

This document contains forward-looking statements within the meaning of federal securities laws that may include statements regarding intent, belief or current expectations of the Company and its management. These forward-looking statements are not guarantees of future performance and involve a number of risks and uncertainties that may cause our actual results to differ materially from the results discussed in these statements. Factors that might affect our results include, but are not limited to, the ability of irifolven, palonosetron or our other product candidates to be proven safe and effective in humans, to receive marketing authorizations from regulatory authorities and to ultimately compete successfully with other therapies, continued sales of Salagen® Tablets, development or acquisition of additional products, reliance on contract manufacturing, changes in strategic alliances, continued access to capital, and other risks and uncertainties detailed from time to time in our filings with the Securities and Exchange Commission, including Exhibit 99

to the annual report on Form 10-K for the year ended December 31, 2001. We do not intend to update any of the forward-looking statements after the date of the annual report to conform them to actual results.

### Market Risk Considerations

Our operations are not subject to risks of material foreign currency fluctuations, nor do we use derivative financial instruments in our investment practices. We place our marketable investments in instruments that meet high credit quality standards, as specified in our investment policy guidelines. We do not expect material losses with respect to our investment portfolio or exposure to market risks associated with interest rates. The impact on our net loss as a result of a one percent change in short-term interest rates would be approximately \$777,000 based on our cash, cash equivalents and marketable investment balances at December 31, 2001.

# BALANCE SHEETS

December 31,	2000	2001
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 11,031,714	\$ 40,699,408
Cash – restricted	—	4,000,000
Short-term marketable investments	18,867,073	30,006,144
Receivables, less allowances of \$158,579 and \$117,397	2,806,462	1,829,654
Inventories	1,476,275	1,500,054
Prepaid expenses	5,826,260	246,739
Total current assets	40,007,784	78,281,999
Equipment and furniture, at cost less accumulated depreciation of \$1,192,171 and \$1,322,559	1,510,859	3,325,334
Long-term marketable investments	—	3,006,928
Long-term equity investments	3,800,000	6,800,000
Intangible assets, at cost less accumulated amortization of \$98,498 and \$1,280,476	6,993,372	5,811,394
Other assets	431,555	442,368
Total assets	\$ 52,743,570	\$ 97,668,023
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,426,828	\$ 1,674,412
Accrued expenses	11,785,849	12,609,838
Deferred revenue	731,883	794,383
Other current liabilities	21,411	21,857
Total current liabilities	13,965,971	15,100,490
Noncurrent liabilities:		
Long-term deposit payable	1,550,000	3,750,000
Deferred revenue	9,981,982	9,828,223
Other noncurrent liabilities	1,200,000	54,599
Total noncurrent liabilities	12,731,982	13,632,822
Total liabilities	26,697,953	28,733,312
Stockholders' equity:		
Preferred stock, 10,000,000 authorized and unissued shares		
Common stock, \$.01 par value, 30,000,000 authorized shares, 16,509,008 and 25,005,050 issued shares	165,090	250,051
Additional paid-in capital	114,431,198	192,060,653
Accumulated deficit	(88,550,671)	(123,375,993)
Total stockholders' equity	26,045,617	68,934,711
Total liabilities and stockholders' equity	\$ 52,743,570	\$ 97,668,023

See accompanying notes to financial statements.

# STATEMENTS OF OPERATIONS

Year Ended December 31,	1999	2000	2001
<b>Revenues:</b>			
Sales	\$18,643,168	\$ 21,333,229	<b>\$ 30,021,813</b>
Promotion	1,087,852	769,874	<b>—</b>
Licensing	4,954,468	3,109,470	<b>2,932,007</b>
	24,685,488	25,212,573	<b>32,953,820</b>
<b>Costs and expenses:</b>			
Cost of sales	1,208,650	1,626,833	<b>3,632,767</b>
Selling, general and administrative	12,713,287	18,294,757	<b>28,463,387</b>
Research and development	6,677,435	17,241,217	<b>36,101,373</b>
Amortization	—	98,498	<b>1,181,978</b>
	20,599,372	37,261,305	<b>69,379,505</b>
Income (loss) from operations	4,086,116	(12,048,732)	<b>(36,425,685)</b>
Interest income	966,434	2,145,553	<b>1,600,363</b>
Income (loss) before taxes and cumulative effect of change in accounting principle	5,052,550	(9,903,179)	<b>(34,825,322)</b>
Provision for income taxes	321,051	148,000	<b>—</b>
Net income (loss) before cumulative effect of change in accounting principle	4,731,499	(10,051,179)	<b>(34,825,322)</b>
Cumulative effect of change in accounting principle	—	(9,402,643)	<b>—</b>
Net income (loss)	\$ 4,731,499	\$ (19,453,822)	<b>\$ (34,825,322)</b>
Net income (loss) per common share:			
Basic:			
Income (loss) before effect of accounting change	\$ 0.32	\$ (0.63)	<b>\$ (1.74)</b>
Cumulative effect of accounting change	—	(0.59)	<b>—</b>
Net income (loss)	\$ 0.32	\$ (1.22)	<b>\$ (1.74)</b>
Assuming dilution:			
Income (loss) before effect of accounting change	\$ 0.30	\$ (0.63)	<b>\$ (1.74)</b>
Cumulative effect of accounting change	—	(0.59)	<b>—</b>
Net income (loss)	\$ 0.30	\$ (1.22)	<b>\$ (1.74)</b>
Weighted average number of common shares outstanding:			
Basic	14,742,151	15,990,459	<b>19,985,192</b>
Assuming dilution	15,633,120	15,990,459	<b>19,985,192</b>

See accompanying notes to financial statements.

# STATEMENTS OF CASH FLOWS

Year Ended December 31,	1999	2000	2001
<b>Operating Activities:</b>			
Net income (loss)	\$ 4,731,499	\$(19,453,822)	<b>\$(34,825,322)</b>
Adjustments for non-cash items:			
Cumulative effect of change in accounting principle	—	9,402,643	—
Stock issuance for palonosetron license	—	—	<b>2,999,992</b>
Depreciation and intangible amortization	394,201	451,369	<b>1,876,327</b>
Benefit plan contribution	362,087	315,993	<b>836,507</b>
Financing transaction costs	—	—	<b>516,604</b>
Noncash consulting payments	—	42,510	<b>189,747</b>
Deferred rent	—	—	<b>54,599</b>
Stock option acceleration	162,953	—	—
Other	53,791	11,292	<b>100,852</b>
Change in operating assets and liabilities:			
Receivables	(1,017,362)	(378,561)	<b>976,808</b>
Inventories	448,503	(480,584)	<b>(23,779)</b>
Prepaid expenses	176,030	(5,672,337)	<b>5,579,521</b>
Accounts payable and accrued expenses	343,769	4,227,952	<b>4,388,684</b>
Deferred revenue	—	816,222	<b>(91,259)</b>
Other current liabilities	7,071	5,090	<b>446</b>
Net cash provided by (used in) operating activities	5,662,542	(10,712,233)	<b>(17,420,273)</b>
<b>Investing Activities:</b>			
Purchase of investments	(22,393,143)	(42,069,003)	<b>(49,472,664)</b>
Maturity of investments	17,059,879	39,103,255	<b>35,326,665</b>
Acquisition of Hexalen® capsules	—	(1,200,000)	<b>(4,800,000)</b>
Purchase of minority investment in MethylGene	—	(3,800,000)	<b>(3,000,000)</b>
Purchase of equipment and furniture	(783,501)	(836,248)	<b>(2,588,234)</b>
Payments on notes receivable	56,999	—	—
Other	(41,315)	(65,855)	<b>(32,255)</b>
Net cash used in investing activities	(6,101,081)	(8,867,851)	<b>(24,566,488)</b>
<b>Financing Activities:</b>			
Proceeds from issuance of shares, net	—	16,448,138	<b>72,117,460</b>
Restricted cash	—	—	<b>(4,000,000)</b>
Receipt of deposit payable	—	1,550,000	<b>2,200,000</b>
Issuance of shares under stock plans	2,174,583	4,364,412	<b>1,336,995</b>
Net cash provided by financing activities	2,174,583	22,362,550	<b>71,654,455</b>
Increase in cash and cash equivalents	1,736,044	2,782,466	<b>29,667,694</b>
Cash and cash equivalents at beginning of year	6,513,204	8,249,248	<b>11,031,714</b>
Cash and cash equivalents at end of year	\$ 8,249,248	\$ 11,031,714	<b>\$ 40,699,408</b>
Supplemental disclosure of cash information:			
Cash paid for income taxes	\$ 240,000	\$ 176,975	<b>\$ 2,000</b>
Supplemental disclosure of non-cash investing activities:			
Included in accrued liabilities at December 31, 2001 is \$1,200,000 of the \$7,200,000 purchase price for the acquisition of Hexalen capsules.			

See accompanying notes to financial statements.



## STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock	Additional paid-in capital	Notes receivable from officers	Accumulated deficit	Total stockholders' equity
<b>Balance at December 31, 1998</b>	\$ 145,425	\$ 90,850,590	\$(56,999)	\$ (73,828,348)	\$ 17,110,668
Exercise of stock options, 386,006 shares	3,860	2,021,544	—	—	2,025,404
Employee stock purchase plan, 18,189 shares	182	161,704	—	—	161,886
Employee retirement savings plan contribution, 32,973 shares	329	394,641	—	—	394,970
Note payment	—	—	56,999	—	56,999
Stock option acceleration	—	162,953	—	—	162,953
Net income	—	—	—	4,731,499	4,731,499
<b>Balance at December 31, 1999</b>	149,796	93,591,432	—	(69,096,849)	24,644,379
Issuance of 1,000,000 shares	10,000	16,438,138	—	—	16,448,138
Exercise of stock options, 503,036 shares	5,030	4,046,784	—	—	4,051,814
Employee stock purchase plan, 25,077 shares	251	312,347	—	—	312,598
Other issuances, 1,255 shares	13	42,497	—	—	42,510
Net loss	—	—	—	(19,453,822)	(19,453,822)
<b>Balance at December 31, 2000</b>	165,090	114,431,198	—	(88,550,671)	26,045,617
Issuance of 4,000,000 shares	40,000	29,128,655	—	—	29,168,655
Issuance of 3,025,000 shares	30,250	31,086,712	—	—	31,116,962
Issuance of 900,000 shares	9,000	11,822,843	—	—	11,831,843
Issuance for technology license, 297,338 shares	2,973	2,997,019	—	—	2,999,992
Exercise of stock options, 175,885 shares	1,759	861,138	—	—	862,897
Employee retirement savings plan contribution, 38,226 shares	383	553,235	—	—	553,618
Employee stock purchase plan 45,457 shares	455	473,643	—	—	474,098
Financing transaction costs	—	516,604	—	—	516,604
Other issuances, 14,136 shares	141	189,606	—	—	189,747
Net loss	—	—	—	(34,825,322)	(34,825,322)
<b>Balance at December 31, 2001</b>	<b>\$250,051</b>	<b>\$192,060,653</b>	<b>\$ —</b>	<b>\$(123,375,993)</b>	<b>\$68,934,711</b>

See accompanying notes to financial statements.

# NOTES TO FINANCIAL STATEMENTS

1

## Summary of Significant Accounting Policies

MGI PHARMA, Inc. (MGI or the Company) is an oncology-focused pharmaceutical company that acquires, develops and commercializes proprietary products that address unmet needs of cancer patients. The Company focuses its direct sales efforts solely within the United States and creates alliances with other pharmaceutical or biotechnology companies for the commercialization of its products in other countries.

The Company promotes products directly to physician specialists in the United States using its own sales force. These products include Company-owned Salagen® Tablets (pilocarpine hydrochloride), Hexalen® (altretamine) capsules, and Didronel® (etidronate disodium) IV infusion. The Company also sells Mylocel™ (hydroxyurea) tablets under an exclusive marketing and distribution agreement with Barr Laboratories. Salagen Tablets are approved in the United States for two indications: the symptoms of dry mouth associated with radiation treatment in head and neck cancer patients and the symptoms of dry mouth associated with Sjögren's syndrome, an autoimmune disease that damages the salivary glands. Sales of Salagen Tablets in the United States accounted for 87 percent of product sales during 2001. Hexalen capsules, which the Company began selling since it acquired the product from MedImmune Inc. in November 2000, is an orally-administered chemotherapeutic agent approved in the United States for treatment of refractory ovarian cancer patients. Didronel IV infusion is approved for the treatment of hypercalcemia (elevated blood calcium) in late-stage cancer patients. Mylocel tablets are approved for the treatment of melanoma, resistant chronic myelocytic leukemia, and recurrent, metastatic, or inoperable carcinoma of the ovary.

Outside the United States, MGI commercializes its products through various alliances and recognizes licensing revenues. MGI has licensing agreements with several international pharmaceutical companies to develop and commercialize Salagen Tablets in Europe, Canada and Japan. Exclusive rights in Japan to irofulven and the other acylfulvene analogs were granted to Dainippon under a development and commercialization agreement in 1995. MGI relies on third parties to manufacture its commercialized and development stage products.

In April 2001, MGI obtained the exclusive U.S. and Canadian license and distribution rights to palonosetron, a cancer supportive care product candidate for the prevention of chemotherapy-induced nausea and vomiting, which recently completed its Phase 3 trials. The Company's current product development efforts also include a series of clinical trials for irofulven, the lead product candidate in MGI's novel family of proprietary cancer therapy compounds called the acylfulvenes. MGI is also developing MG98 and other inhibitors of DNA methyltransferase for North American markets. DNA methyltransferase is an enzyme that has been associated with uncontrolled tumor growth. In addition, MGI also provides ongoing clinical support of Salagen Tablets.

## Cash, Cash Equivalents and Investments

The Company considers highly liquid marketable securities with remaining maturities of ninety days or less at the time of purchase to be cash equivalents. Other highly liquid marketable securities with remaining maturities of one year or less at the balance sheet date are classified as short-term marketable investments. Long-term marketable investments are highly liquid marketable securities with remaining maturities of more than one year at the balance sheet date.

Short-term and long-term marketable investments are classified as held-to-maturity investments because the Company has the intent and the ability to hold its investments to maturity. As such, they are stated at amortized cost, which approximates estimated fair value. Amortized cost is adjusted for amortization of premiums and discounts to maturity, and this amortization is included in interest income in the accompanying statements of operations.

## Concentration of Credit Risk

Financial instruments that may subject the Company to significant concentrations of credit risk consist primarily of short-term and long-term marketable investments and trade receivables.

Cash in excess of current operating needs is invested in accordance with the Company's investment policy. This policy emphasizes principal preservation, so it requires strong issuer credit ratings and limits the amount of credit exposure from any one issuer or industry.

The Company grants credit primarily to pharmaceutical wholesale distributors throughout the United States in the normal course of business. Five wholesalers accounted for approximately 93 percent of Company sales in 2001. Customer credit-worthiness is routinely monitored and collateral is not normally required.

#### **Concentration of Supply Risk**

MGI depends on a single supplier to provide the active ingredient for Salagen Tablets, which accounted for 87 percent of the Company's product sales during 2001. If this supplier ends its relationship with MGI, or is unable to meet the Company's demand for the ingredient, MGI may be unable to produce Salagen Tablets for commercial sale.

#### **Inventories**

Inventories are stated at the lower of cost or market. Cost is determined on a first-in, first-out basis.

#### **Long-term Equity Investments**

MGI owns a \$6,800,000 minority investment in MethylGene Inc., a privately-held Canadian biopharmaceutical company. \$3,800,000 was purchased in conjunction with the license of North American rights to MG98 and other product candidates in 2000. An additional \$3,000,000 was purchased in 2001. This minority investment is carried at cost. The valuation of this minority investment is periodically reviewed for impairment based upon the results of operations and financial position of MethylGene, as well as the value of any sales of its shares.

#### **Sales Revenue Recognition**

Sales and related costs are recognized upon shipment of product to customers. Sales are recorded net of provisions for pricing adjustments, collection discounts and product returns.

#### **Promotion Revenue Recognition**

Promotion revenue is recognized when the service has been performed or product sales have occurred which result in a fixed and determinable promotion fee being payable to MGI without a right to refund. Under promotion arrangements, the other party to the agreement recognizes product sales and MGI recognizes promotion revenue.

#### **Licensing Revenue Recognition**

The Company implemented Staff Accounting Bulletin No. 101 "Revenue Recognition in Financial Statements" (SAB 101), in the fourth quarter of 2000 with retroactive effect to January 1, 2000. Under SAB 101, the Company recognizes revenue from licensing arrangements using a contingency-adjusted performance model. Under this method, revenue related to up-front, time-based, and performance-based licensing payments is recognized over the entire contract performance period. The Company recognizes the aggregate of non-refundable up-front and time-based fees ratably over the effective term of the underlying license and related supply arrangements. Performance-based, contingent license payment amounts are recognized on a pro rata basis in the period the licensee achieves the performance criteria to the extent of the timing of the achievement of the milestone in relation to the term of the underlying arrangements – approximating the extent of contingent performance through the date of the milestone achievement in relation to the full term of the underlying arrangements. The Company recognizes the remaining portion of any milestone payments over the remaining term of the underlying arrangements. Payments received by the Company in excess of amounts earned are classified as deferred revenue. Further, the Company recognizes royalties on product sales and support services provided to strategic partners in licensing revenue when the related sales or provision of services occur.

Prior to the implementation of SAB 101, the Company recognized licensing revenue when underlying performance criteria for payment had been met and when the Company had an unconditional right to such payment. Depending on a license agreement's terms, recognition criteria may have been satisfied upon achievement of milestones, passage of time or product sales by the licensee.

The Company recorded a one-time, non-cash charge and corresponding increase in deferred revenue of \$9.4 million as a result of the cumulative effect of the adoption of SAB 101 as of January 1, 2000. Amounts previously recognized as revenue, but deferred as a result of the implementation of SAB 101, will be amortized into future license revenue over the expected period of benefit from these collaborative arrangements. The Company recognized \$841,258 of amortized deferred revenue in 2001. At December 31, 2001, the Company has an unamortized deferred revenue balance of \$10,622,606.

**Stock-Based Compensation**

The Company applies the intrinsic value method described in Accounting Principles Board (APB) Opinion No. 25 in accounting for the issuance of stock incentives to employees and directors. Accordingly, as all grants are made at or above the market price, no compensation expense has been recognized in the financial statements. In accordance with Statement of Financial Accounting Standards No. (SFAS) 123, "Accounting for Stock Based Compensation," pro forma information reflecting compensation cost for such issuances is presented in the Stockholders' Equity footnote.

**Advertising and Promotion Expense**

Costs of advertising and promotion are expensed as incurred and were \$1,801,341, \$2,824,053 and \$4,933,137 in 1999, 2000 and 2001, respectively. The Company does not defer any costs related to direct-response advertising.

**Depreciation**

Fixed assets consist of equipment, furniture and leasehold improvements. Depreciation of equipment and furniture is provided over the estimated useful lives of the respective assets on a straight-line basis. Estimated useful lives of equipment and furniture range from three to ten years. Leasehold improvements are amortized over the shorter of the lease term or the useful life of the improvements.

**Research and Development**

Research and development costs are expensed as incurred. Costs of in-licensing payments for drugs that have not yet reached market approval are expensed as research and development.

**Amortization**

Amortization of intangible assets relating to the purchase of the Hexalen capsules business is recognized as the greater of the amount computed on a straight-line basis over the six year estimated commercial life of Hexalen capsules or in proportion to the actual product contribution compared to estimated product contribution over the estimated commercial life of Hexalen capsules.

**Income Taxes**

Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is carried against deferred tax assets until it is deemed more likely than not that some portion or all of the deferred tax assets will be realized.

**Income (Loss) Per Common Share**

Basic earnings per share (EPS) is calculated by dividing net income (loss) by the weighted-average common shares outstanding during the period. Diluted EPS reflects the potential dilution to basic EPS that could occur upon conversion or exercise of securities, options, or other such items to common shares using the treasury stock method based upon the weighted-average fair value of the Company's common shares during the period. During net loss periods, other potentially dilutive securities are not included in the calculation of net loss per share since their inclusion would be anti-dilutive.

**Use of Estimates**

Preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions affecting reported asset and liability amounts and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

**Basis of Presentation**

Certain prior year amounts have been reclassified to conform to current year presentation.

**New Accounting Pronouncements**

SFAS 141, "Business Combinations," requires use of the purchase method of accounting for business combinations initiated after June 30, 2001. Use of the pooling-of-interests method is prohibited. The adoption of SFAS 141 did not have any impact on the financial position or results of operations of the Company.

SFAS 142, "Goodwill and Other Intangible Assets," changes the accounting for goodwill from an amortization method to an impairment-only approach. Amortization of goodwill, including goodwill in past business combinations, will therefore cease upon adoption of SFAS 142. As of January 1, 2002, the date of adoption of SFAS 142, the Company has unamortized identifiable intangible assets of \$5,811,394 that are subject to the provisions of SFAS 142. The Company does not have any transitional impairment losses. The adoption of SFAS 142 did not have a material impact on the financial position or results of operations of the Company because the identifiable intangible assets will continue to be amortized.

SFAS 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," addresses the financial accounting and reporting for the impairment of long-lived assets. The adoption of SFAS 144 on January 1, 2002, did not have any impact of the financial position or results of operations of the Company.

EITF 00-14, "Accounting for Certain Sales Incentives," provides guidance on the accounting for sales incentives the companies offer to their customers. EITF 00-14 does not have any material impact on the Company.

EITF 00-25, "Vendor Income Statement Characterization of Consideration Paid to a Reseller of the Vendor's Products," provides guidance for consideration that vendors give to resellers of the vendor's products. EITF 00-25 has no impact on the Company.

## 2

### Investments

Marketable investments consist of held-to-maturity investments and are stated at amortized cost, which approximates estimated fair value. Short-term marketable investments at December 31, 2000 and 2001 are summarized as follows:

	2000	2001
Commercial paper	\$13,333,117	<b>\$13,898,548</b>
Medium-term notes	—	<b>16,107,596</b>
Certificates of deposit	5,533,956	—
	<b>\$18,867,073</b>	<b>\$30,006,144</b>

Long-term marketable investments consist of certificates of deposit that mature in January 2003.

## 3

### Inventories

Inventories at December 31, 2000 and 2001 are summarized as follows:

	2000	2001
Raw materials and supplies	\$ 339,039	<b>\$ 50,458</b>
Work in process	699,598	<b>445,429</b>
Finished products	437,638	<b>1,004,167</b>
	<b>\$1,476,275</b>	<b>\$1,500,054</b>

## 4

### Prepaid Expenses

Prepaid expenses at December 31, 2000 and 2001 are summarized as follows:

	2000	2001
Other prepaids	\$ 826,260	<b>\$246,739</b>
Palonosetron letter of intent deposit	5,000,000	—
	<b>\$5,826,260</b>	<b>\$246,739</b>

## 5

### Accrued Expenses

Accrued expenses at December 31, 2000 and 2001 are summarized as follows:

	2000	2001
Product development commitments	\$ 3,500,784	<b>\$ 4,503,281</b>
Bonuses	889,499	<b>1,774,916</b>
Hexalen capsules business purchase obligation	4,800,000	<b>1,200,000</b>
Lease accrual	—	<b>983,271</b>
Product return accrual	600,768	<b>963,430</b>
Other accrued expenses	1,994,798	<b>3,184,940</b>
	<b>\$11,785,849</b>	<b>\$12,609,838</b>

## Leases

The Company leases office space under noncancellable lease agreements that contain renewal options and require the Company to pay operating costs, including property taxes, insurance and maintenance. In January 2001, the Company executed a lease agreement for new office space, beginning in May 2001. At December 31, 2001, the Company has an accrual of \$983,271 for lease obligations for the former office space in excess of estimated sublease rental income. Rent expense was \$408,163, \$455,364 and \$2,233,988 in 1999, 2000 and 2001, respectively.

Future minimum lease payments under noncancellable leases, including both the current and former office spaces, are as follows:

2002	\$1,575,000
2003	1,601,000
2004	1,622,000
2005	1,498,000
2006	1,229,000
Thereafter	1,776,000
	<u>\$9,301,000</u>

## Licensing Arrangements

### Technology Out-License Arrangements

During 1995, MGI entered into a cooperative development and commercialization agreement with Dainippon Pharmaceutical Co., Ltd., whereby MGI granted Dainippon an exclusive license to develop and commercialize acylfulvenes, including irofulven, in Japan. Dainippon granted MGI an irrevocable, exclusive, royalty-free license allowing MGI to use any technology or data developed by Dainippon relating to the acylfulvenes. If a resulting product has not been launched in Japan by October 2005, MGI may terminate the license unless Dainippon elects to make license continuation payments on a quarterly basis. Under this agreement, Dainippon paid initial and continuing quarterly milestone payments totaling \$11.1 million through April 2000. Dainippon will make a \$1 million milestone payment upon receipt of the approval to market the first acylfulvene product in Japan. Also under the

terms of the agreement, from April 2000 through December 31, 2001, \$3.8 million in deposit payments were paid by Dainippon, with the remaining \$0.5 million deposit paid in January 2002. MGI's repayment of these deposit amounts is due upon receipt of initial marketing approval in Japan. Dainippon may elect to receive the deposit repayment in cash, as a credit toward delivery of bulk drug substance, or in shares of MGI common stock. Dainippon also agreed to pay MGI a portion of any non-royalty payments made by a sublicensee to Dainippon. Unless terminated earlier by the parties for cause or by mutual agreement, the term of the agreement is for the longer of the applicable patents in Japan, or ten years from the date of the last regulatory approval in Japan. Thereafter, the agreement automatically renews for additional one-year periods. Dainippon may terminate the agreement before receipt of marketing authorization upon six months prior written notice, or after receipt of marketing authorization for competitive reasons upon one year prior written notice.

In addition, MGI entered into a supply agreement with Dainippon in October 1995 pursuant to which MGI participates in the commercialization of the product and agrees to supply Dainippon's requirements of the product during the term of the development, marketing and cooperation agreement described above. Dainippon agrees to make certain minimum purchase requirements during the first four years and as agreed upon by the parties thereafter.

Under a November 1994 license agreement with Pharmacia Corporation, MGI granted an exclusive, royalty-bearing license to develop and commercialize Salagen Tablets in Canada. Pharmacia granted MGI an irrevocable, non-exclusive, royalty-free license allowing MGI to use any technology or data developed by Pharmacia. Pharmacia paid MGI a \$75,000 initial fee and agreed to pay MGI royalties equal to a percentage of Pharmacia's net Salagen Tablet sales revenues, subject to annual minimum requirements. MGI also agreed to supply Pharmacia's requirement of Salagen Tablets until the termination of the license agreement with Pharmacia, or the termination of MGI's agreement with Merck KgaA, whichever is earlier. In addition, MGI agreed to pay Pharmacia royalties if MGI promotes Salagen Tablets in Canada in the first or second year following termination of the agreement. After the initial commercial period concludes in January 2004, either party may terminate the agreement upon one year prior written notice. The agreement automatically expires in January 2006 unless extended by the parties.

In December 1994, MGI entered into a license agreement with Kissei Pharmaceutical Co., Ltd., a pharmaceutical company in Japan. Under the terms of the agreement, MGI granted an exclusive, royalty-bearing license to develop and commercialize Salagen Tablets in Japan. Kissei granted back to MGI an irrevocable, non-exclusive, royalty-free license allowing MGI to use any technology or data developed by Kissei related to Salagen Tablets. Kissei paid MGI an initial license fee and subsequent milestone payments that aggregated to \$2.5 million through December 31, 2001. There are no additional milestone payments due under the agreement. In addition, Kissei agreed to pay MGI royalties equal to a percentage of Kissei's Salagen Tablets net sales revenue. Unless earlier terminated by the parties for cause or by mutual agreement, the term of the agreement is for ten years from the date Salagen Tablets are launched in Japan. Thereafter, the agreement automatically renews for additional one-year periods.

In April 2000, MGI entered into a license agreement with Novartis Ophthalmics AG under which MGI granted Novartis an exclusive, royalty-bearing license to develop and commercialize Salagen Tablets in Europe, Russia and certain other countries. Novartis granted MGI an irrevocable, non-exclusive, royalty-free license allowing MGI to use any technology developed by Novartis related to Salagen Tablets. In addition, MGI simultaneously entered into a supply agreement with Novartis pursuant to which MGI agreed to supply Novartis' requirements of Salagen Tablets until termination of the license agreement with Novartis. The term of the license agreement is 12 years and is thereafter automatically extended for additional two-year terms unless otherwise terminated in writing by either party. Either party may terminate the license agreement for cause. In addition, Novartis may terminate the license agreement if the supply agreement is terminated and Novartis has not been supplied with Salagen Tablets for a period of more than 180 days. Simultaneous with this agreement, the previous agreements with Chiron B.V. for Salagen Tablets rights in Europe were terminated. Sales of Salagen Tablets in Europe began in 1995.

A \$750,000 net license fee was received in June 2000 upon receipt of regulatory qualification for Novartis to sell the product in the UK, and an additional \$750,000 net license fee was received in April 2001 upon satisfaction of certain regulatory approvals or transfers. These amounts are being amortized to licensing revenue over the 12-year term of the agreement. The agreement includes milestone payments which are due if certain annualized and cumulative net sales thresholds are achieved. Royalty payments, based on a percentage of net sales revenue, continue for the term of the agreement.

#### **Technology In-License Arrangements**

To build its product pipeline, the Company acquires rights to develop and market pharmaceutical products from others. Under this approach, the Company may be required to pay upfront, development services and milestone fees. In addition, the Company may be required to pay royalties on net sales upon marketing the products. Within a period of time after providing notice, the Company generally may terminate its licenses. All material, noncancellable commitments were recognized as of December 31, 2001.

In August 2000, MGI entered into a License, Research and Development Agreement (the License Agreement) and a Stock Purchase Agreement (the Purchase Agreement) with MethylGene Inc. Under the Purchase Agreement, MGI purchased a minority investment in MethylGene for \$3.8 million and made an additional purchase of MethylGene shares for \$3.0 million in April 2001. Under the License Agreement, MethylGene granted MGI an exclusive, royalty-bearing license to develop and commercialize MG98 in North America for all therapeutic indications. The License Agreement also included a license for similar rights to small molecule inhibitors of DNA methyltransferase. In exchange, MGI agreed to make initial payments to MethylGene aggregating \$5.7 million and agreed to purchase up to \$6 million of research services from MethylGene. Milestone payments are payable to MethylGene based on achievement of development milestones for MG98 and other DNA methyltransferase inhibitors. MGI also agreed to pay royalties on annual net sales revenue related to MG98 and other DNA methyltransferase inhibitors. The term of the License Agreement extends until the later of the expiration of the last-to-expire patent that MGI has licensed or ten years after

the first commercial sale of any licensed product. Either party may terminate the License Agreement in the event of a breach or bankruptcy by the other party. In addition, after the License Agreement has been in effect for two years, MGI may terminate the agreement on a licensed-product-by-licensed-product basis for any reason upon 90 days notice to MethylGene.

In January 2001, MGI entered into an agreement with Barr Laboratories, Inc. for the exclusive marketing and distribution rights for Mylocel tablets (hydroxyurea) in the United States. Mylocel tablets are approved for the treatment of melanoma, resistant chronic myelocytic leukemia, and recurrent, metastatic, or inoperable carcinoma of the ovary. MGI began marketing and distributing Mylocel tablets in March 2001. Under the terms of the agreement, Barr Laboratories receives payments based upon the product contribution derived from MGI's sale of product. MGI gave notice to terminate this agreement effective April 2002.

In April 2001, MGI obtained the exclusive North American license and distribution rights for palonosetron from HELSINN Healthcare SA. Palonosetron is a 5-HT<sub>3</sub> antagonist with an extended half-life for the prevention of chemotherapy-induced nausea and vomiting, which has completed its Phase 3 clinical trials. The \$11 million in upfront payments made by MGI were funded using the \$5 million deposit made upon the execution of the letter of intent in October 2000, \$3 million in cash paid in April 2001, and \$3 million of MGI's common shares delivered in April 2001. An additional \$2 million milestone was paid in October 2001. Milestone payments aggregating to \$25 million will become payable upon achievement of underlying development objectives, culminating with marketing approval of palonosetron in the United States. Under the terms of the agreement, MGI placed \$4 million into an escrow account to fund the next milestone payment. HELSINN will continue to fund and conduct all development of palonosetron.

## 8

### Promotion Revenue

In 2001, MGI concluded its promotion agreement with Pharmacia for the co-promotion of Azulfidine EN-tabs® (sulfasalazine delayed release tablets, USP) Enteric-coated. MGI did not recognize any promotion revenue under this agreement.

In September 2000, MGI concluded its promotion agreement with Connetics Corporation for the promotion of Ridaura® (auranofin). Under the terms of the agreement, MGI

recognized \$750,000 per quarter through September 30, 2000 for making a minimum number of sales calls related to this rheumatology product.

In March 1999, MGI concluded its promotion agreement with Schein Pharmaceutical, Inc. for the promotion of INFeD® (iron dextran injection). Under the agreement, the Company recognized a final minimum quarterly promotion fee of \$125,000 in the first quarter of 1999, and smaller promotion fees based upon product sales amounts for the remaining three quarters of 1999.

## 9

### Stockholder Rights Plan

Each outstanding share of common stock of the Company has one preferred share purchase right (Right) per share. Each Right entitles the registered holder to purchase one one-hundredth of a share of Series A Junior Participating Preferred Stock, at a price of \$200 per one-hundredth of a preferred share (subject to adjustment). The Rights become exercisable only if certain change in ownership control events occur and the Company does not redeem the Rights. The Rights expire on July 14, 2008, if not previously redeemed or exercised.

## 10

### Stockholders' Equity

#### Stock Offerings

In May 2000, the Company completed a public offering of 1,000,000 newly issued shares of common stock at \$18 per share. The net proceeds to the Company, after fees and expenses, were \$16,448,138.

In May 2001, the Company completed a sale of 4,000,000 newly issued shares of common stock to U.S. Bancorp Piper Jaffray Inc., which offered the shares at the public offering price of \$8 per share. The net proceeds to the Company, after fees and expenses, were \$29,168,655.

In October 2001, the Company completed a private placement of 3,025,000 newly issued shares of common stock to accredited investors at \$11 per share. The net proceeds to the Company, after fees and expenses, were \$31,116,962.



In November 2001, the Company completed a sale of 900,000 newly issued shares of common stock to U.S. Bancorp Piper Jaffray Inc., which offered the shares at the public offering price of \$13.25 per share. The net proceeds to the Company, after fees and expenses, were \$11,831,843.

#### Stock Incentive Plans

Under stock incentive plans, designated persons (including officers, employees, directors and consultants) have been or may be granted rights to acquire Company common stock. These rights include stock options and other equity rights. At December 31, 2001, 3,667,977 shares of common stock remain reserved for issuance, of which 283,649 shares remain available for grant.

Stock options become exercisable over varying periods and expire up to ten years from the date of grant. Options may be granted in the form of incentive stock options or nonqualified stock options. The option price for incentive stock options cannot be less than fair market value on the date of the grant. The option price for nonqualified stock options may be set by the board of directors.

Stock option activity in the three years ended December 31, 2001 is summarized as follows:

	Number of Shares	Average Price Per Share
Outstanding at December 31, 1998	2,187,476	\$ 6.33
Granted	548,711	11.78
Exercised	(386,006)	5.21
Canceled	(246,047)	9.77
Outstanding at December 31, 1999	2,104,134	7.56
Granted	713,040	20.76
Exercised	(503,036)	8.05
Canceled	(50,372)	13.08
Outstanding at December 31, 2000	2,263,766	11.48
Granted	1,373,919	13.47
Exercised	(175,885)	4.91
Canceled	(77,472)	17.27
<b>Outstanding at December 31, 2001</b>	<b>3,384,328</b>	<b>\$12.49</b>

The following table summarizes information concerning options outstanding and exercisable at December 31, 2001:

Range of Exercise Price	Options Outstanding		Options Exercisable		
	Number Outstanding	Weighted Average Remaining Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$3.38-\$4.38	369,118	5.51	\$3.93	313,435	\$3.93
\$4.44-\$6.00	432,959	4.52	\$4.98	425,509	\$4.97
\$7.00-\$10.13	188,234	8.40	\$9.13	46,519	\$8.02
\$10.25	489,933	9.16	\$10.25	6,000	\$10.25
\$10.31-\$12.94	476,609	7.23	\$11.73	212,281	\$11.78
\$13.00-\$16.44	571,075	7.55	\$15.91	181,537	\$15.33
\$16.69-\$17.94	636,400	9.01	\$16.77	10,000	\$16.75
\$18.25-\$51.50	220,000	8.14	\$29.96	59,990	\$29.15
Total	3,384,328	7.49	\$12.49	1,255,271	\$8.75

#### Employee Stock Purchase Plan

Under the Company's employee stock purchase plan, substantially all employees may purchase shares of common stock at the end of semi-annual purchase periods at a price equal to the lower of 85 percent of the stock's fair market value on the first or last day of that period. Plan funding occurs throughout the purchase period by pre-elected payroll deductions of up to 15 percent of regular pay. No compensation expense results from the plan. Shares issued under the plan were 18,189, 25,077 and 45,457 at average prices of \$8.90, \$12.47 and \$10.43 per share in 1999, 2000 and 2001, respectively. At December 31, 2001, 56,444 shares remain reserved for future issuance under the plan.

#### Fair Value of Stock Plans

The Company applies APB Opinion No. 25 in accounting for its stock incentive plans for designated persons and, accordingly, as all grants are made at or above the market price on the date of the grant, no compensation cost has been recognized in the financial statements for employee and director stock options granted under its stock plans. Had the Company determined compensation cost based on the fair value at the grant date for its stock options and the fair value of the discount related to the employee stock purchase plan under SFAS 123, the Company's net income (loss) would have been reported as shown below:

	1999	2000	2001
Net income (loss):			
As reported	\$4,731,499	\$(19,453,822)	<b>\$(34,825,322)</b>
Pro forma	\$2,853,476	\$(24,856,197)	<b>\$(43,909,133)</b>
Net income (loss) per common share:			
As reported diluted	\$ 0.30	\$ (1.22)	<b>\$ (1.74)</b>
Pro forma diluted	\$ 0.18	\$ (1.55)	<b>\$ (2.20)</b>

The per share weighted-average fair value of stock options granted during 1999, 2000 and 2001 was \$6.50, \$14.03 and \$9.00, respectively, on the date of grant, using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	1999	2000	2001
Expected dividend yield	0%	0%	<b>0%</b>
Risk-free interest rate	5.00%	4.80%	<b>4.30%</b>
Annualized volatility	0.60	0.80	<b>0.80</b>
Expected life, in years	5	5	<b>5</b>

#### Retirement Savings Plan

The Company's retirement savings plan conforms to Section 401(k) of the Internal Revenue Code and participation is available to substantially all employees. Under the savings plan, participants may contribute a percentage of their eligible compensation for investment in Company common stock or other investment vehicles. The Company matches a portion of employees' contributions and may also make discretionary contributions ratably to all eligible employees. Company contributions are made in the form of Company common stock and become fully vested when an employee attains five years of service. Participants may direct the investment of Company contributions to any of the plan's investment options after full vesting of those contributions. Contribution expense was \$362,087, \$315,993 and \$836,507 in 1999, 2000 and 2001, respectively. The Company had 178,568 shares reserved for future issuance under the savings plan at December 31, 2001.

#### Preferred Stock

At December 31, 2001, 10,000,000 shares of preferred stock remained issuable. Issuance is subject to board of directors' action.

#### Other

At December 31, 2001, 100,000 shares remain registered for sale from shelf registration statements that were filed for 5 million shares with the Securities and Exchange Commission. These remaining shares pertain to an option that we granted to Ramius Securities to purchase 100,000 shares of our common stock at prices ranging from \$16.95 to \$24.72 per share. This option, which expires on February 28, 2003, relates to a financing facility with Ramius Securities, LLC, and Ramius Capital Group, LLC. Upon depletion of the shares available from the shelf registration, and absent current plans to utilize the Ramius financing facility, we expensed all deferred financing costs related to this facility in the fourth quarter of 2001. We recognized a non-cash charge of \$516,604 in selling, general and administrative expense for the value of the stock option as determined at the initiation of the financing facility.

**11****MGI Funded Retirement Trust**

The Company sponsors a money purchase retirement plan covering substantially all employees. Under the plan, the Company contributes a percentage of participating employees' eligible compensation. Company contributions resulted in expense of \$203,724, \$184,634 and \$367,881 in 1999, 2000 and 2001, respectively.

**12****Income Taxes**

The provision for income taxes differs from statutory federal income tax rates in the years ended December 31, 1999, 2000 and 2001 as follows:

	1999	2000	2001
Statutory federal income tax rate	\$ 1,717,867	\$(3,367,082)	<b>\$(11,840,609)</b>
Foreign tax	145,200	97,680	—
Valuation allowance change	(1,833,215)	3,857,787	<b>14,248,689</b>
Research activities credit	(172,570)	(255,380)	<b>(791,797)</b>
Orphan drug credit	(386,357)	(993,878)	<b>(1,868,469)</b>
State income taxes, net of federal benefit	126,314	(247,579)	<b>(870,633)</b>
Net operating loss expiration	484,007	1,052,891	<b>1,193,570</b>
Other	239,805	3,561	<b>(70,751)</b>
	<b>\$ 321,051</b>	<b>\$ 148,000</b>	<b>\$ —</b>

Deferred taxes as of December 31, 2000 and 2001 consist of the following:

	2000	2001
Deferred tax assets:		
Receivable allowances	59,467	<b>44,024</b>
Inventory allowances	7,777	<b>116,472</b>
Product return allowance	225,288	<b>361,286</b>
Miscellaneous accrued expenses	79,180	<b>480,068</b>
Deferred revenue	4,017,699	<b>3,983,478</b>
Amortization of intangibles	22,162	<b>288,107</b>
Net operating loss carryforward	32,046,857	<b>43,014,788</b>
Research credit carryforward	2,600,581	<b>3,392,378</b>
Orphan drug credit	2,115,265	<b>3,983,734</b>
Alternative minimum tax credit carryforward	48,295	<b>100,270</b>
	41,222,571	<b>55,764,605</b>
Less valuation allowance	(41,157,794)	<b>(55,589,132)</b>
	<b>64,777</b>	<b>175,473</b>
Deferred tax liabilities:		
Tax depreciation greater than book	64,777	<b>175,473</b>

The Company maintains a valuation allowance to fully reserve against its deferred tax assets due to uncertainty over the ability to realize these assets. As of December 31, 2000 and December 31, 2001, the valuation allowances were \$41,157,794 and \$55,589,132, respectively. Of these amounts, \$4,652,978 for the year ended December 31, 2000, and \$4,835,626 for the year ended December 31, 2001, were attributable to increases in the net operating loss carryover resulting from the exercise of stock options. These amounts will be recorded as a credit to additional paid-in capital if it is determined in the future that this portion of the valuation allowance is no longer required.

At December 31, 2001, the Company had net operating loss carryforwards of approximately \$114,700,000 for federal income tax purposes, which continue expiring in 2002. The Company also had a credit for alternative minimum tax of \$100,270 which has no expiration date. Additionally, the Company had research credit carryforwards of approximately \$3,392,000, and orphan drug credit carryforwards of approximately \$3,984,000 which continue expiring in 2002.

**13****Income (Loss) Per Common Share**

Income (loss) per share for the years ended December 31, 1999, 2000 and 2001 is based on weighted average shares outstanding as summarized in the following table:

Year Ended December 31,	1999	2000	2001
Weighted-average shares – basic	14,742,151	15,990,459	<b>19,985,192</b>
Effect of dilutive stock options	890,969	—	—
Weighted-average shares – assuming dilution	15,633,120	15,990,459	<b>19,985,192</b>

The total number of options excluded from the calculation of potentially dilutive securities either because the exercise price exceeded the average market price or because their inclusion in a calculation of net loss per share would have been anti-dilutive were 232,087, 2,263,766 and 3,384,328 for 1999, 2000 and 2001, respectively.

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#### Related Party Transactions

One of the Company's directors, who became a director in May 1998, is the managing partner of Boston Healthcare Associates, a biotechnology consulting partner for the Company. The Company made payments to Boston Healthcare of \$87,000, \$172,000 and \$101,000 in 1999, 2000 and 2001, respectively. Transactions with Boston Healthcare were in the ordinary course of business at prices comparable to transactions with other companies.

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#### Segment and Geographical Information

The Company operates in a single operating segment of specialty pharmaceuticals. Essentially all of its assets are located in the United States. Operating revenues attributable to the U.S. and foreign customers in the years ended December 31, 1999, 2000 and 2001 are as follows:

	1999	2000	2001
United States	\$21,229,185	\$23,259,190	<b>\$30,573,044</b>
Japan	2,476,474	1,154,315	<b>701,033</b>
Other Foreign	979,829	799,068	<b>1,679,743</b>
	<b>\$24,685,488</b>	<b>\$25,212,573</b>	<b>\$32,953,820</b>

Other foreign areas include Canada, Colombia, Egypt, Europe, Hong Kong (People's Republic of China), Israel, Korea, Singapore and Taiwan.

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#### Product Acquisition

On November 21, 2000, MGI acquired certain assets and assumed certain liabilities related to the business associated with the product Hexalen (altretamine) capsules from MedImmune Inc. The \$7,091,870 excess of the \$7.2 million purchase price over the \$108,130 fair value of the net assets acquired was allocated to intangible assets. Amortization is recognized as the greater of the amount computed on a straight-line basis over six years, which is the estimated commercial life of Hexalen capsules, or in proportion to the actual product contribution compared to the estimated product contribution over the estimated commercial life of Hexalen capsules. Under the terms of the agreement, royalties are due to MedImmune on quarterly net sales of Hexalen capsules for a period of ten years.

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#### Research and Development Expense

Research and development expense for the years ended December 31, 1999, 2000 and 2001 consists of the following:

	1999	2000	2001
License payments	\$ 50,000	\$ 5,975,000	<b>\$13,066,250</b>
Other research and development	6,627,435	11,266,217	<b>23,035,123</b>
	<b>\$6,677,435</b>	<b>\$17,241,217</b>	<b>\$36,101,373</b>

# INDEPENDENT AUDITORS' REPORT

## **The Board of Directors and Stockholders**

### **MGI PHARMA, Inc.:**

We have audited the accompanying balance sheets of MGI PHARMA, Inc. as of December 31, 2001 and 2000, and the related statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of MGI PHARMA, Inc. as of December 31, 2001 and 2000, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2001 in conformity with accounting principles generally accepted in the United States of America.

**KPMG LLP**

**KPMG LLP**

**February 8, 2002**

# OFFICERS AND DIRECTORS

## Officers

### **Charles N. Blitzer**

President and  
Chief Executive Officer

### **William C. Brown**

Chief Financial Officer  
and Secretary

### **Alan R. Caplan**

Vice President,  
Sales

### **Michael T. Cullen Jr., M.D.**

Vice President,  
Clinical Affairs and  
Chief Medical Officer

### **Robert M. Johnson**

Vice President,  
Manufacturing and  
International Operations

### **John R. MacDonald, Ph.D.**

Senior Vice President,  
Research and Development

### **Leon O. Moulder, Jr.**

Executive Vice President

### **Edgar F. Timberlake**

Vice President,  
Human Resources  
and Administration

## Board of Directors

### **Hugh E. Miller**

Chairman of the Board  
Retired Vice Chairman and Director,  
ICI Americas Inc.

### **Charles N. Blitzer**

President and Chief Executive Officer and Director,  
MGI PHARMA, Inc.

### **Andrew J. Ferrara**

President and Chief Executive Officer,  
Boston Healthcare

### **Philip S. Schein, M.D.**

President (USA), International Network  
for Cancer Treatment and Research;  
President, The Schein Group;  
Adjunct Professor of Medicine and Pharmacology,  
University of Pennsylvania School of Medicine

### **Lee J. Schroeder**

President and Director,  
Lee Schroeder & Associates, Inc.

### **David B. Sharrock**

Adjunct Professor, The Ohio State University College of  
Pharmacy; Research Committee Member, Cincinnati  
Children's Hospital Medical Center

### **Arthur L. Weaver, M.D.**

Director, Clinical Research,  
The Arthritis Center of Nebraska;  
Clinical Professor, Department of Medicine,  
University of Nebraska Medical Center

# SHAREHOLDER INFORMATION

## Market Price and Related Matters

## For MGI PHARMA Information



## Transfer Agent and Registrar

## Stock Price Range

## Form 10-K

## Patient and Physician Information

## Independent Auditors

## Legal Counsel

## Annual Meeting



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